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UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

EASTERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

CALIFORNIA STEM CELL TREATMENT CENTER, INC., *et al.*

Defendants.

No. 5:18-CV-01005-JGB-KKx

PLAINTIFF'S RESPONSE TO DEFENDANTS' NOTICE OF RECENT DECISION

Trial: May 4 – 13, 2021

Honorable Jesus G. Bernal
United States District Judge

PLAINTIFF'S RESPONSE TO DEFENDANTS' NOTICE OF RECENT DECISION

Plaintiff United States of America respectfully submits this response to the Notice of Recent Decision filed by Defendants in connection with *United States v. California Stem Cell Treatment Center, Inc*. ECF No. 175. In their Notice of Recent Decision, Defendants submitted for this Court's consideration a D.C. Circuit opinion in *The Judge Rotenberg Educ. Ctr., Inc. v. United States Food & Drug Admin.*, Case No. 20-1087, -- F.4th -- 2021 WL 2799891, at *1 (D.C. Cir. July 6, 2021). Contrary to Defendants' representation, *Rotenberg* does not address any legal issues currently pending before this Court.

In *Rotenberg*,[1] a divided D.C. Circuit panel held that under section 516 of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360f , FDA may not ban a medical device for a particular use while allowing that device to continue to be lawfully marketed and distributed for different intended uses. The *Rotenberg* majority held that a ban based on a device's particular use would impermissibly regulate healthcare practitioners' ability to prescribe the device for that use, and would conflict with a different section of the FDCA that codified the practice of prescribing medical devices for off-label use, 21 U.S.C. § 396 ("Nothing in this Act shall . . . limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient…"). *See Rotenberg*, 2021 WL 2799891, at *1.

The instant case, however, does not pertain to FDA's authority to ban a medical device under 21 U.S.C. § 360f. Nor are all devices used by Defendants to manufacture their stromal vascular fraction drug products legally marketed devices. Indeed, one of the primary devices Defendants use in the manufacturing process – namely, the Time Machine device – has not been cleared or approved by FDA. *See* Plaintiff's Revised

[1] The time for seeking further review of the panel's opinion in *Rotenberg* has not yet run.

[Proposed] Findings of Fact and Conclusions of Law, ECF No. 169-1 ¶¶ 190-195 (providing citations to trial evidence establishing that Time Machine is not now and never has been cleared or approved by FDA). Further, none of Defendants' three drugs and biological products at issue in this case is approved by FDA for any use. For the same reasons set forth in Plaintiff's Revised [Proposed] Findings of Fact and Conclusions of Law, Defendants' practice of medicine defense fails. *See* ECF 169-1 ¶¶ 86-87.

Dated: August 6, 2021

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 6th day of August 2021, I electronically filed a true and correct copy of the foregoing PLAINTIFF'S RESPONSE TO DEFENDANTS' NOTICE OF RECENT DECISION through the Court's CM/ECF system, which will send a notice of electronic filing to the following counsel of record listed below:

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